

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 2 of 20

**Listing of Claims:**

1. (Currently Amended) An apparatus for placing a proximal portion of a needle in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area by a manipulation device, the needle having a translational axis, said apparatus comprising:

a first arm being configured and arranged to rotatably support a distal portion of the needle about its translational axis;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the needle along its translational axis in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

wherein the first arm and first drive mechanism are coupled to the manipulation device such that the manipulation device can position the apparatus in proximity to the entry point of the object containing the target area; and

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about translational axis of the needle; and

a second arm spaced apart from the first arm, configured and arranged to support a proximal portion of the needle, said second arm being aligned with the first arm so that the first arm and distal portion of the needle are movable toward the second arm.

2. (Previously presented) The apparatus of claim 16, wherein the first arm is further configured and arranged to rotatably support the needle about the translational axis of the needle; and wherein the apparatus further comprises:

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle.

3. (Previously presented) The apparatus of claim 2 wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the needle are separately and independently controlled.

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 3 of 20

4. (Previously presented) The apparatus of claim 2, wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the needle are performed at the same time.

5. (Previously presented) The apparatus of claim 2, wherein the first and second drive mechanisms are configured and arranged so as to do one of translating of the first arm or rotating of the needle.

6. (Previously presented) The apparatus of claim 2, wherein the second drive mechanisms is configured and arranged so as to selectively rotate the needle at one of a number of different rotational speeds.

7. (Currently amended) The apparatus of claim 16, wherein the further comprising a second arm is coupled to the first drive mechanism so that the first arm translates towards the second arm.

8. (Previously presented) The apparatus of claim 7, in which the second arm further includes a guide mechanism in which the needle is moveably received.

9. (Previously presented) The apparatus of claim 8, wherein the guide mechanism is selectively configurable so as to be capable of guiding differently sized needles.

10. ((Previously presented) The apparatus of claim 16, wherein the first arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the first arm.

11. (Original) The apparatus of claim 7, wherein the second arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the second arm.

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 4 of 20

12. (Previously presented) The apparatus of claim 11 wherein the detachable portion includes at least a portion of a guide mechanism in which the needle is moveably received.

13. (Previously presented) The apparatus of claim 16, wherein the first drive mechanisms includes a slipless transmission assembly.

14. (Previously presented) The apparatus of claim 16, wherein the first drive mechanism comprises a screw mechanically coupled to the first arm such that rotation of the screw causes the first arm to translate from the first position.

15. (Original) The apparatus of claim 14, wherein the first drive mechanism further includes a bi-directional motor coupled to the screw and wherein the first arm can be translated in one of two direction responsive to the direction of rotation of the motor.

16. (Currently Amended) An apparatus for placing a proximal portion of a needle in a target area, the needle having a translational axis, comprising:

a first arm being configured and arranged to rotatably support a distal portion of the needle about the translational axis of the needle;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area; and

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates; and

a second arm spaced apart from the first arm, configured and arranged to support a proximal portion of the needle, said second arm being aligned with the first arm so that the first arm and distal portion of the needle are movable toward the second arm.

17. (Original) The apparatus of claim 16, wherein the linear guide comprises:

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 5 of 20

a rod member;  
a track;  
a sliding member a portion of which is configured to slidably engaged the track and which is secured to the first arm; and  
a coupling mechanism secured to the sliding member and slidably coupling the rod member to the sliding member.

18. (Original) The apparatus of claim 2, further comprising:  
a controller that is configured and arranged to selectively and separately control the first and second drive mechanisms.

19. (Previously Presented) The apparatus of claim 18, wherein the controller is further configured so as to include a plurality of pre-established needle driving protocols for driving the needle end portion from an initial position to the target area.

20. (Previously Presented) The apparatus of claim 18, wherein the controller is configured and arranged so that translating of the first arm and rotating of the needle are performed at the same time.

21. (Previously Presented) The apparatus of claim 18, wherein the controller is configured and arranged so as to do one of translating of the first arm or rotating of the needle.

22. (Previously Presented) The apparatus of claim 18, wherein the controller is configured and arranged so as to selectively rotate the needle at one of a number of different rotational speeds.

23. (Previously Presented) The apparatus of claim 18, wherein the controller is configured and arranged so as to successively translate the needle in a back and forth manner.

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 6 of 20

24. (Previously Presented) The apparatus of claim 18 further comprising a sensor and wherein the controller is configured and arranged to alter the needle driving protocol based on signals from the sensor.

25. (Previously Presented) The apparatus of claim 16, wherein the needle is configured so as to be capable of performing any one of injecting therapeutic agents into the target area, locating an imaging device in the target area, biopsy including tissue biopsy, and locating a medical device in the target area to be used to perform a medical procedure.

26. (Previously presented) An apparatus for placing a proximal portion of a needle in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the needle having a translational axis, said apparatus comprising:

- a first arm being configured and arranged to rotatably support the needle about the translational axis of the penetrating member;

- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the needle along its translational axis in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

- a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle; and

- wherein the second drive mechanism comprises a gear member secured to the needle and being mechanically coupled to a motor such that operation of the motor causes the needle to rotate about its translational axis.

27. (Canceled)

28. (Previously Presented) The apparatus of claim 56, wherein the motor is a bi-directional motor and wherein the penetrating member can be rotated in one of a clockwise and counter clockwise direction responsive to the direction of rotation of the motor.

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 7 of 20

29. (Currently Amended) An apparatus for placing a proximal portion of a needle in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the needle having a translational axis, said apparatus comprising:

a first arm being configured and arranged to rotatably support a distal portion of the needle about the translational axis of the needle;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the needle proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates;

a second arm spaced apart from the first arm, configured and arranged to support a proximal portion of the needle, and coupled to the first drive mechanism so that the first arm translates towards the second arm; and

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle.

30. (Previously Presented) The apparatus of claim 29 wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the needle are separately and independently controlled.

31. (Previously Presented) The apparatus of claim 29, wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the needle are performed at the same time.

32. (Previously Presented) The apparatus of claim 29, wherein the first and second drive mechanisms are configured and arranged so as to do one of translating of the first arm or rotating of the needle.

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 8 of 20

33. (Previously Presented) The apparatus of claim 29, wherein the second drive mechanisms is configured and arranged so as to selectively rotate the needle at one of a number of different rotational speeds.

34. (Previously Presented) The apparatus of claim 29, in which the second arm further includes a guide mechanism in which the needle is moveably received.

35. (Original) The apparatus of claim 29, wherein:  
the first arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the first arm; and  
the second arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the second arm.

36. (Original) The apparatus of claim 29, wherein the first drive mechanism comprises:  
a screw mechanically coupled to the first arm such that rotation of the screw causes the first arm to translate from the first position;  
a bi-directional motor coupled to the screw; and  
wherein the first arm is translated in one of two direction responsive to the direction of rotation of the motor.

37. (Canceled)

38. (Previously Presented) The apparatus of claim 29, wherein the linear guide comprises:  
a rod member;  
a track;  
a sliding member a portion of which is configured to slidably engaged the track and which is secured to the first arm; and

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 9 of 20

a coupling mechanism secured to the sliding member and slidably coupling the rod member to the sliding member.

39. (Original) The apparatus of claim 29, further comprising a controller that is configured and arranged to selectively and separately control the first and second drive mechanisms.

40. (Canceled)

41. (Previously Presented) The apparatus of claim 57, wherein the motor is a bi-directional motor and wherein the penetrating member can be rotated in one of a clockwise and counter clockwise direction responsive to the direction of rotation of the motor.

42. (Previously Presented) An apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body, the needle having a translational axis, said apparatus comprising:

a first arm being configured and arranged to rotatably support the needle about the translational axis of the needle;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the needle proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm;

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates;

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle; and



D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 10 of 20

wherein the second arm further includes a guide mechanism in which the needle is moveably received.

43. (Original) The apparatus of claim 42, wherein:

the first arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the first arm; and

the second arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the second arm.

44. (Previously presented) An apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body, said apparatus comprising:

a first arm being configured and arranged to rotatably support the needle about the translational axis of the needle;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm;

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle;

wherein the second arm further includes a guide mechanism in which the needle is moveably received; and

wherein the first drive mechanism comprises:

a screw mechanically coupled to the first arm such that rotation of the screw causes the first arm to translate from the first position;

a bi-directional motor coupled to the screw;

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 11 of 20

wherein the first arm is translated in one of two direction responsive to the direction of rotation of the motor; and

a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates, wherein the linear guide includes:

a rod member,

a track,

a sliding member a portion of which is configured to slidably engaged the track and which is secured to the first arm, and

a coupling mechanism secured to the sliding member and slidably coupling the rod member to the sliding member.

45. (Previously presented) An apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body, said apparatus comprising:

a first arm being configured and arranged to rotatably support the needle about the translational axis of the needle;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, , thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm;

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle;

wherein the second arm further includes a guide mechanism in which the needle is moveably received; and

wherein the second drive mechanism comprises:

a gear member secured to the penetrating member;

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 12 of 20

a drive gear that is mechanically coupled to the motor and the penetrating member gear member so that the penetrating member gear member rotates responsive to rotation of the motor; wherein the motor is a bi-directional motor; and wherein the penetrating member can be rotated in one of a clockwise and counter clockwise direction responsive to the direction of rotation of the motor.

46. (Currently Amended) A method for localizing a proximal portion of a needle in a target area of a body, the needle having a translational axis, comprising the steps of:

supporting a distal portion of the needle from a first arm and a proximal portion of the needle from a second arm;

positioning the first arm and second arm with respect to the body so the translational axis of the needle passes through the target area;

linearly translating the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the needle proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area; and rotating the needle about the translational axis of the needle.

47. (Canceled)

48. (Previously Presented) The method of claim 46, wherein said steps of rotating said needle and translating the first arm are concurrently performed as the needle proximal portion is translated through a surface of the body.

49. (Previously Presented) The apparatus of claim 1, wherein the first arm is operably coupled to the manipulation device that positions the first arm with respect to the entry point of the object containing the target area so a long axis of the needle passes through the target area.

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 13 of 20

50. (Previously Presented) The apparatus of claim 29, wherein the first arm is operably coupled to an apparatus that positions the first arm with respect to the entry point of the object containing the target area so a long axis of the needle passes through the target area.

51. (Previously Presented) The apparatus of claim 42, wherein the first arm is operably coupled to an apparatus that positions the first arm with respect to the entry point of the object containing the target area so a long axis of the needle passes through the target area.

52. (Previously Presented) The apparatus of claim 1, wherein the first drive mechanism is configured and arranged to translate the first arm so that the needle proximal portion moves along a translation axis that passes through the target area.

53. (Currently Amended) The apparatus of claim 29, wherein the first drive mechanism is configured and arranged to translate the first arm so that the ~~penetrating~~ penetrating member proximal portion moves along a translation axis that passes through the target area.

54. (Previously Presented) The apparatus of claim 42, wherein the first drive mechanism is configured and arranged to translate the first arm so that the needle moves along a translation axis that passes through the target area.

55. (Canceled)

56. (Previously Presented) An apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the penetrating member having a translational axis, said apparatus comprising:

a first arm being configured and arranged to rotatably support the penetrating member about the translational axis of the penetrating member;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 14 of 20

from the initial position, thereby also translating the penetrating member along its translational axis in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area;

a second drive mechanism being coupled to the penetrating member and being configured and arranged so as to cause the penetrating member to rotate about the translational axis of the penetrating member; and

wherein the second drive mechanism comprises a gear member secured to the penetrating member and being mechanically coupled to a motor such that operation of the motor causes the penetrating member to rotate about its translational axis,

wherein the second drive mechanism further includes a drive gear that is mechanically coupled to the motor and the penetrating member gear member so that the penetrating member gear member rotates responsive to rotation of the drive gear.

57. (Currently Amended) An apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the penetrating member having a translational axis, said apparatus comprising:

a first arm being configured and arranged to rotably support the penetrating member about the translational axis of the penetrating member;

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area;

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates;

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm; and

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 15 of 20

a second drive mechanism being coupled to the penetrating member and being configured and arranged so as to cause the penetrating member to rotate about the translational axis of the penetrating member,

the second drive mechanism comprising a gear member secured to the penetrating member, and a drive gear that is mechanically coupled to the motor and the penetrating member gear member so that the penetrating member gear member rotates responsive to rotation of the motor.

58. (New) The apparatus of claim 1, wherein the second arm further includes a guide mechanism in which the needle is moveably received, and which is arranged and configured to restrain the movement of the needle to its translational axis..

59. (New) An apparatus for placing an end of an elongated tissue penetrating member into a target area by longitudinal translation of the tissue penetrating member in a desired travel path comprising:

a first arm arranged and configured to grasp a distal portion of the tissue penetrating member;

a first drive mechanism coupled to the first arm and arranged and configured to translate the first arm from an initial position to a secondary position toward the target area, thereby also longitudinally translating the tissue penetrating member toward the target area; and

a second arm spaced apart from the first arm, arranged and configured to support a proximal portion of the tissue penetrating member, said second arm including a guide mechanism in which the tissue penetrating member is moveably received, and which is arranged and configured to restrain the movement of the tissue penetrating member to translation along its longitudinal axis.

60. (New) The apparatus of claim 59, wherein the first and second arms are configured and arranged such that the first arm and distal portion of the tissue penetrating member translate toward the second arm.

D. Stoianovici, et al.  
U.S.S.N.: 09/943,751  
Page 16 of 20

61. (New) The apparatus of claim 59, further comprising a second drive mechanism coupled to the tissue penetrating member, and arranged and configured to cause the tissue penetrating member to rotate about the translational axis of the tissue penetrating member.

62. (New) The apparatus of claim 61, wherein the second drive mechanism comprises a first motor-driven gear member coupled to a second gear member secured to the tissue penetrating member, causing the tissue penetrating member to rotate about its translational axis in response to rotation of the motor.